3. Cancelled

4. Cancelled

5. Cancelled

B2 Sub C1

8. The formulation of claim [4] 1, wherein said formulation additionally comprises excipients, lubricants, binders or glidants.

Sub C1 B3

17. An extended release pharmaceutical active formulation comprising;

- a capsule, tablet, pellet or bead of about 5-95% by weight pharmaceutical active, about 0-60% by weight pharmaceutical compression aid selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar, and about 0-50% by weight pharmaceutical extrusion aid.

- an encasement coat comprising one or more layers of a polymeric film encasing said capsule, tablet, pellet or bead, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

18. Cancelled

20. Cancelled

Sub C1 B4

25. The formulation of claim [3] 1, wherein less than about 20% of the pharmaceutical active is released in one hour when tested in a USP type 2 apparatus at 75 rpm in 900ml simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and greater than 80% of the pharmaceutical active is released in one hour when tested in a USP type 2 apparatus at 75 rpm in 900ml simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C.

26. The formulation of claim 1, wherein the tablet or pellet is made by direct compression.

B5 Sub C1

29. The formulation of claim 1, wherein said capsule, tablet, pellet or bead demonstrates

extended release characteristics of greater than 4 hours when tested in a USP type 2 apparatus at 75 rpm in 900mls simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and demonstrates extended release characteristics of greater than 4 hours when tested in a USP type 2 apparatus at 75 rpm in 900mls simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C

31. A method for making an extended release pharmaceutical active formulation comprising;

- compressing about 5-95% by weight pharmaceutical active into a capsule, tablet or pellet with an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

- encasing said tablets, pellets or beads in an encasement coat comprising one or more layers of a polymeric film, said encasement coat soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer of polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

32. The method of claim 31, wherein said pharmaceutical compression aid is present in an amount of about 0-60% by weight and said pharmaceutical extrusion aid is present in an amount of about 0-50% by weight.

Remarks

Claims 1, 3-9, 11, 12, and 14-18 and 20-33 are presently before the Examiner. Claims 1, 14, 17, 25, 26, 29, 31 and 32 have been amended. Claims 3, 4, 5, 12, 13, 14, 18, 19 and 20 have been cancelled without prejudice.

The Examiner is thanked for indicating the allowability of claims 5, 11, 14-16 and 20 if amended to include all of the limitations of the base claims and any intervening claims. These claims have been amended as such and therefore are allowable. As amended, claims dependent from claims 1 (directly or indirectly), 17 and 31 should also be allowable.